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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,666	10/18/2004	Milton L. Brown	00769-07	4259

34444 7590 05/16/2008
UNIVERSITY OF VIRGINIA PATENT FOUNDATION
250 WEST MAIN STREET, SUITE 300
CHARLOTTESVILLE, VA 22902

EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

MAIL DATE	DELIVERY MODE
05/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,666	BROWN, MILTON L.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *3 and 16-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-6,10-15 and 19* is/are rejected.

7)☒ Claim(s) *7-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10/18/2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1-19 are pending.

Claims 1-2, 4-6,10-15 and 19 are rejected.

Claims 7-9 are objected.

Claims 3, and 16-18 have been withdrawn from consideration.

Claim Objections

Claims 7-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 1-2, 4-15 and 19 under 35 U.S.C. 112, second paragraph, has been withdrawn due to the modification of claims.

Claim Rejections - 35 USC § 102

Applicants' argument filed 11/27/2007 have been fully considered but are not persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. The rejection of Claims 1-2, 4-5, and 10 under 35 U.S.C. 102(b) as being anticipated clearly by Meza-Toledo, S.E. et al (Drug Research , vol. 40, p. 1289-1291) has been withdrawn due to the modification of claims.

2. The rejection Claims 1-2, 4-5, and 10 under 35 U.S.C. 102(b) as being anticipated clearly by Meza-Toledo, S.E. et al (Drug Research , vol. 45, p. 756-759) has been changed to the rejection of Claims 1-2, 4-5, and 10-13 under 35 U.S.C. 103(a) as being unpatentable over Meza-Toledo, S.E. et al (Drug Research , vol. 45, p. 756-759).

3. The rejection of Claims 1-2, 4-6, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Sandoval et al (WO 99/41229) has been changed to the rejection of Claims 1-2, 4-6, and 10-13 under 35 U.S.C. 103(a) as being unpatentable over Sandoval et al (WO 99/41229).

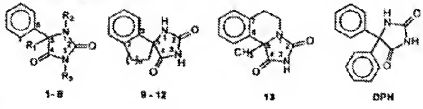
4. The rejection of Claims 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Grunewald et al (Tetrahedron Letters, 1980, 21(13) p.1219-1220) has been withdrawn due to the modification of claims.

5. The rejection of Claims 1-2, 4-5, 10, and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Brown et al (J. Med. Chem.. 1999, 42, p. 1537-45) has been changed to the rejection of Claims 1-2, 4-5, 10, 13-15 and 19 under 35 U.S.C. 102(b) as being anticipated clearly by Brown et al (J. Med. Chem. 1999, 42, p. 1537-45).

6. Claims 1-2, 4-5, 10, 13-15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated clearly by Brown et al (J. Med. Chem.. 1999, 42, p. 1537-45).

Brown et al discloses the following compounds (see page 1538, table 1) :

Table 1. Data from the PLS Cross-Validated Analysis



compd	R_1	R_2	R_3	n
1	*n*-propyl	H	H	
2	*n*-butyl	H	H	
3	*n*-butyl	H	methyl	
4	*n*-pentyl	H	H	
5	*n*-hexyl	H	H	
6	*n*-heptyl	H	H	
7	*n*-nonyl	H	H	
8a	methyl	ethyl	H	
8b	methyl	ethyl	H	
9a				1
9b				1
10a				2
10b				2
11a				3
11b				3
11c				3
11d				3
11e				3
11f				3
12a				4
12b				4
12c				4
12d				4
12e				4
13a				
13b				
DPH	phenyl	H	H	

This is identical with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

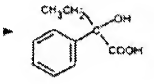
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-2, 4-5, and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meza-Toledo, S.E. et al (Drug Research , vol. 45, p. 756-759).

Meza-Toledo, S.E. et al discloses the following compound (see page 757, at the top) :

.



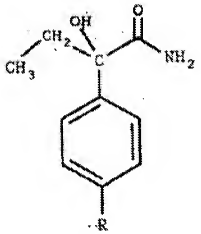
However, the instant invention differs from the prior art in that the claimed R has C1 alkyl or C3-C6 alkyl unlike the prior art compound which has the R has C2 alkyl.

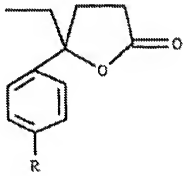
Even so, the Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood,* 199 USPQ 137; *In re Hoke,* 195 USPQ 148; *In re Lohr,* 137 USPQ 548; *In re Magerlein,* 202 USPQ 473; *In re Wiechert,* 152 USPQ 249; *Ex parte Henkel,* 130 USPQ 474; *In re Fauque,* 121 USPQ 425; *In re Druey,* 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change the prior art compound to the claimed compound since it seems reasonable to prepare the claimed compound in the same method and they share generally the same properties between them.

8. Claims 1-2, 4-6, and 10-13 under 35 U.S.C. 103(a) as being unpatentable over Sandoval et al (WO 99/41229).

Sandoval et al discloses the following compound (see figures 3 and 4) :





R= F DL-F-HEPA

R= Cl DL-Cl-HEPA

However, the instant invention differs from the prior art in that the claimed R has C1 alkyl or C3-C6 alkyl unlike the prior art compound which has the R has C2 alkyl.

Even so, the Compounds that differ only by the presence or absence of an extra methyl group or two are homologues. Homologues are of such close structural similarity that the disclosure of a compound renders *prima facie* obvious its homologue. The homologue is expected to be prepared by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing homologues. Of course, these presumptions are rebuttable by the showing of

unexpected effects, but initially, the homologues are obvious even in the absence of a specific teaching to add or remove methyl groups. See *In re Wood,* 199 USPQ 137; *In re Hoke,* 195 USPQ 148; *In re Lohr,* 137 USPQ 548; *In re Magerlein,* 202 USPQ 473; *In re Wiechert,* 152 USPQ 249; *Ex parte Henkel,* 130 USPQ 474; *In re Fauque,* 121 USPQ 425; *In re Druey,* 138 USPQ 39. In all of these cases, the close structural similarity between two compounds differing by one or two methyl groups was itself sufficient show obviousness. See also MPEP 2144.09, second paragraph.

Therefore, it would have been obvious to the skilled artisan in the art to be motivated to change the prior art compound to the claimed compound since it seems reasonable to prepare the claimed compound in the same method and they share generally the same properties between them.

Applicants' Argument

Applicants argue the following issues:

a. The amending the alkyl group of R by deleting C_2 and C_7, amending "n" of the R_2 constituent "$(CH_2)_nCONHR_{10}$ " to consisting of just 3 or 4 will overcome all the prior art rejections.

Applicants' arguments have been noted, but the arguments are not persuasive.

First, regarding the applicants' argument , the Examiner has noted applicants' arguments. However, as indicated in the above, even with all the modifications of the claims in the amendment, there are still other issues to be resolved ; therefore, some of the prior art rejections are still applicable. Therefore, applicants' argument is not persuasive.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD,LAC
Primary Examiner
Art Unit: 1625

/Taylor Victor Oh/

Primary Examiner, Art Unit 1625

5/10/08